This Page Is Inserted by IFW Operations and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents will not correct images, please do not report the images to the Image Problem Mailbox.

Food Freshness and 'Smart' Packaging

By Carol Lewis

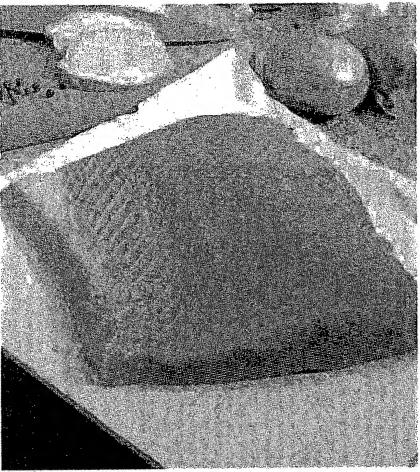
JEFFERSON, Ark. — What could a roll of new carpeting possibly have in common with a slab of smelly, old salmon? They both emit chemically similar vapors—the carpet, as it's being installed; the fish, as it rots.

Chemists here at the Food and Drug Administration's National Center for Toxicological Research (NCTR) have identified "volatile amines" not only as the toxic connection between two seemingly unrelated products, but ultimately as a potential link to determining at what point a food product begins to deteriorate.

Food freshness is a key characteristic of overall food quality. And overall food quality is the result of all the desirable characteristics that make food acceptable to eat. Therefore, being able to tell when food is fresh is vitally important, at home, in a grocery store, or when dining out.

Seafood, for example, is one of the most difficult foods to keep fresh. Millions of bacteria are present on the surface, on the gills, and in the gut of virtually all seafood species. If you know when and where the fish was caught, you might be able to make an educated guess as to its freshness, provided that it's been properly stored. Inspecting the fish for color, resilience and sliminess would help. So might a check of its eyes to determine clarity and sheen. But in the end your nose might determine whether or not you buy the fish. If you're trying to determine whether to buy a piece of fish tightly wrapped in plastic and sitting on a Styrofoam tray, however, the decision might be more difficult. .

The freshness and overall quality of



PhotoDisc

food depend, in large part, on the distribution and marketing systems. Any mishandling of a food along the way can have a significant impact on its overall quality. To further ensure that food retains its high quality, consumers must practice careful food storage and handling habits at home, as well

New technologies are emerging that aim to monitor temperature and

other important variables that play critical roles in determining food freshness. It is hoped that such technologies will be useful in evaluating freshness during the movement of food from producer to supplier to consumers.

How Food Quality Deteriorates

A walk through any grocery store indicates the diversity of today's food

Food Preservation

All foods eventually spoil if not preserved. The basic idea behind the different forms of food preservation is either to slow down the activity of bacteria, or to kill the bacteria altogether. In certain cases, a preservation technique also may destroy enzymes naturally found in a food that cause it to spoil or discolor quickly. Some of the most common methods for preserving foods are:

 Refrigeration and freezing: Slows bacterial action so that it takes food much longer (a week or two, rather than half a day) to spoil, or stops bacterial action altogether. Once a product is thawed, however, the bacteria can become active again, multiplying under the right conditions. Enzyme activity is slowed down but not stopped dur-

ing freezing.

- Canning: Provides a way to store foods for extremely long periods of time. Food is first boiled to destroy bacteria and inactivate enzymes. It is then placed in an airtight container. As the food cools, a vacuum seal is formed that prevents any new bacteria from getting in. Since the food in the container is completely sterile, it does not spoil. Once the container is opened, however, bacteria enter and begin growing in the food. Any unused portions then must be refrigerated.
- Drying (dehydration): Removes most of the moisture from foods. This method kills or completely inactivates bacteria. Dried foods should be stored in airtight containers. This process may alter the taste and texture of some foods, but in many cases, a new and better taste has been created. Examples are powdered milk, potatoes in a box, dried fruits and vegetables, pasta, and rice.
- Irradiation: Exposes certain types of foods to a source of ionizing energy. Unlike canning, the taste is not altered when food is irradiated.

Source: United States Department of Agriculture

Food Safety and Inspection Service

supply—raw vegetables, baked goods, packaged meats, seafood, and more. The selection is a chef's delight. But that diversity also contributes to the challenges of ensuring that food is healthful and wholesome. Delight can become disappointment if undesirable changes in color, flavor, odor, or texture occur. For the most part, this deterioration is caused by enzymes-either contained within the food or produced by microorganisms, such as bacteria, yeasts and molds growing in the food.

Each food type and bacterium produce different chemicals or classes of chemicals. The chemicals produced vary and include volatile bases, volatile acids, volatile aldehydes, and volatile mercaptans, or sulfur com-

pounds.

Spoilage bacteria (rather than disease-causing "pathogenic" bacteria) usually cause food to deteriorate most quickly because of their short reproduction times. They multiply very rapidly by a process called cell replication or binary fission—one cell divides and becomes two. If conditions such as moisture and temperature are right, for example, certain bacteria can reproduce in as little as 20 minutes. Within 20 minutes, one cell can become two; in 40 minutes, there would be four, and so on. The bacteria are slow to start, but the number increases quickly.

Some bacteria need only about four hours to adapt to a new environment before they begin rapid growth and threaten the window of time that a food item maintains its taste, texture, and nutritional value, known as shelf life. When it comes to food, this means consumers can have less than four hours to make a decision about whether to cool it, heat it, or eat it.

As the bacteria grow, the amount of enzymes produced by those bacteria increases. Enzymes are a normal component of food that help speed up or slow down chemical reactions. The enzymes in a banana, for example, cause it to change color from green to yellow, and then brown to black, as it matures. The ripening and softening of other fruits, such as peaches, tomatoes and apples, are other examples of enzyme action. Heat inactivates these enzymes, which explains why people might blanch vegetables. Cold temperatures also can inactivate enzymes, which is why you would refrigerate certain foods.

In addition, food may deteriorate as a result of chemical changes within the food itself or, more broadly, from

temperature abuse.

"The odor that everyone associates with bad food is rancidity," says Dwight Miller, Ph.D., a chemist at NCTR. Rancidity, also called staleness, is caused by a chemical reaction that breaks down the molecular chains that make up fatty acids in fat to compounds called aldehydes, and may continue to smaller-sized fatty acids, resulting in the release of offensive or musty odors. So, as butter ages, it tastes stronger, just as peanuts become rancid with time.

In some cases, food deterioration may occur before flavor or odor changes are detectable. And because everyone doesn't have the same level of odor-detecting ability, Miller points out, "the untrained nose is not consistent."

A smoker, or even a woman wearing perfume, for example, can temporarily have a reduced ability to smell some odors. That's why, according to Miller, "We have to have a way that consumers can be taught to protect themselves from food that's gone—or is going—bad."

The numbers of microorganisms or enzymes present on a food product determine the degree of food spoilage. Since we cannot see them to count the number growing in our food, next to our untrained noses, we must rely on distributors, manufacturers, and grocers to provide us with some assurance that the products we purchase are fresh.

How Reliable is Current Technology?

Product dating is the most widely used means for consumers to determine when to purchase or use a food product at its best quality. Dates stamped on packages also help the

26 / September-October 2002 / FDA Consumer

store determine how long to display the product for sale. But according to the United States Department of Agriculture (USDA), these dates are not safety dates. Instead, they should be seen as more of a good-faith promise of freshness.

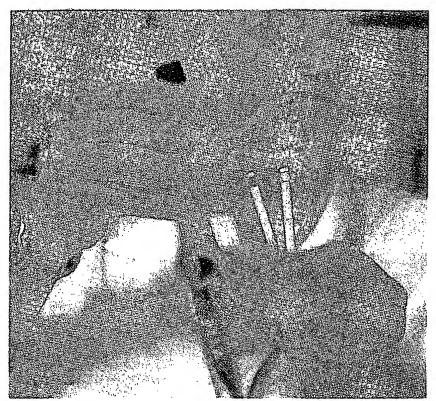
There is no uniform or universally accepted system of food dating in the United States. There are areas where much of the food supply has some type of readily understood calendar date (open dating), rather than a code understood only by the manufacturer and others in the industry (closed dating). Although dating of some foods is required by more than 20 states, in some areas of the country, almost no food products are dated. Except for infant formula and some baby foods, which are regulated by the FDA, product dating is not required by federal regulations.

Open dating is found primarily on perishable foods, such as meat, poultry, eggs, and dairy products. There is no regulation requiring meat products to have a calendar date, but manufacturers sometimes choose to use it voluntarily. The USDA says that if a federally inspected establishment has voluntarily placed a calendar date on meat products, some rules will apply. For example, such a date cannot be removed or changed by a retailer while the product remains in its original packaging.

Whenever a calendar date is used on meats, poultry, and eggs, the USDA also requires that it must express both the month and day of the month. The year is included on products that may be stored for longer times, such as those that are frozen. If a calendar date is shown, a "sell by" or "use before" phrase must accompany that date. (See "The Facts About Food Product Dating," page 29.)

Closed or coded dating might appear on shelf-stable products, such as canned or boxed foods. Since product dating is not used consistently on food products, this practice often confuses or misleads consumers.

A recent report on NBC's "Dateline" uncovered the questionable practice by several national grocery



Black Star/Willie Allen

Dwight Miller, Ph.D., a chemist at the FDA's National Center for Toxicological Research in Jefferson, Ark., checks the color of the dye used in a food quality indicator developed at the center to indicate the freshness of packaged foods.



Miller tests for hydroperoxides in foods, an early indicator of decomposition.

chains of extending sell-by dates on meat products. At one store, the NBC team found that labels bearing a March sell-by date were strategically placed on hams to cover up the original January sell-by date. As a result, thirty-eight days had been added to the original sell-by date. In addition, a test indicated that the hams contained six times the expected bacterial count as a result of the extended time spent on the shelf.

The take-home message? According to "Dateline": Even the sell-by promise is not always a guarantee of food freshness.

The Coming of New Technology

Dwight Miller and two other scientists at the NCTR lab, Jon Wilkes, Ph.D., and Shannon Snellings, Ph.D., used information they learned from the volatile amines detection system to develop a simple but effective way to monitor food freshness. The results? Tiny disks called "food quality indicators" that do what date stamps can't—sense the production of vola-

tile amines. Specifically, they detect the level of amines given off by certain types of seafood, such as shrimp and most types of shellfish and finfish, an indicator of the degree of decomposition.

NCTR Director Daniel A. Casciano, Ph.D., says the concept behind the food quality indicators stemmed from research already being conducted on new carpeting at the lab. The Arkansas facility routinely tests and evaluates not only the safety and hazards of food color additives, drugs, cosmetic chemicals, and other compounds within the FDA's regulatory purview, but also pesticides, airborne contaminants, plastics, synthetic fibers, industrial compounds, and more, as needed by other government agencies.

"Dwight was asked by the Consumer Product Safety Commission (CPSC) to help them identify the vapors that were coming off of new rugs," recalls Casciano. As certain building materials slowly evaporate and break down, they also release

chemicals. There are over 120 different toxic chemicals that may be emitted by carpeting, including formaldehyde, which is used as glue in carpet backing.

"After succeeding in this endeavor," says Casciano, "he theorized that the physical characteristics of the molecules in the new carpeting were similar to those in spoiled fish." Miller explains that the odor from both the carpet and the fish is known as a "volatile," a material that at normal temperatures or under the influence of heat is capable of being vaporized or becoming a gas. "If you can smell the odors," says Miller, "they're in the gas phase."

Casciano says that Miller shrunk the original desk-size analytical detection device used to test the carpet vapors down to what is now a quarter-sized food quality indicator designed to be inserted into food packaging.

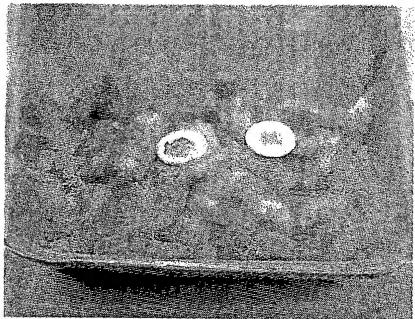
The technology behind the disk is based on a dye locked in a water-repellent material and used as a dot-shaped chemical indicator that changes color as a seafood product decomposes. As the gases from the seafood move through the dot and intermingle with the chemicals, a gradual color change is produced in the disk when a sufficient level of the chemical is present.

At the supermarket, food quality indicators and other products using similar technologies would allow consumers to make rapid and informed decisions on food quality.

But Susan Ferenc, Ph.D., senior scientific adviser to the Grocery Manufacturers of America, a trade association in Washington, D.C., is somewhat skeptical.

"Unless it is very clear as to what these disks indicate," she says, "my thinking is that consumers are going to be a bit cautious—and should be, especially given the number of false positives or false negatives that could come with the technology."

At the regulatory level, Miller says that insertion of these indicators in fish products at the point of origin (during processing and packaging) could help FDA inspectors rapidly identify fish products that have



NCTR/Dwight Miller

This plastic-wrapped package of shrimp was bought at a grocery store and kept in a freezer for two days. The shrimp then were thawed in a refrigerator for 56 hours. The food quality indicator on the left was inserted into the package after thawing. Chemical gases in the package caused the indicator to change from yellow to blue in less than an hour, indicating that the shrimp were no longer fresh. The disk on the right was placed outside the package to show the indicator's color in fresh food.

Here's How Long Same Popular Foods Should Be Kept

PRODUCT	STORAGE PERIOD	
	In Refrigerator	In Freezer
Fresh Meat	•	
Beeft		
Ground	1-2 days	3-4 months
Steaks and roasts	3-5 days	6-12 months
Pork:		
Chops	3-5 days	4-6 months
Ground	1-2 days	3-4 months
Roasts	3.5 days	4-6 months
Fish:	•	
Lean (such as cod,	1-2 days	up to 6 months
flounder haddock)	•	
Fatty (such as blue,	1-2 days	2-3 months
perch, salmon)		
Chicken:		
Whole	1-2 days	12 months
Parts	1-2 days	9 months
Giblets	1-2 days	3-4 months
Cured meats		- * ***********************************
Lunch meat	3-5 days	1-2 months
Sausage	1-2 days	1-2 months
Gravy	1-2 days	2-3 months
Dairy Products	, , , , , ,	
Swiss, brick,	3-4 weeks	•
processed cheese		
Milk	5 days	Lmonth
Ice cream, ice milk	- market	2-4 months
Eggs:		
fresh in shell	3 weeks	·
Hard-boiled	1 week	color

[.] Cheese can be frozen, but freezing will affect the texture and taste

Sources: Food Marketing Institute for fish and dairy products, USDA for all other foods.

deteriorated beyond acceptable limits, helping to speed inspections.

The freshness detector system is being tested on shrimp in Canada and the results are very promising, with consumer use expected to follow. But, says Miller, "Since some foods don't decompose by the same mechanisms, the technology still has a way to go." As various toxins become characteristic of one product and then another, the idea will continue to be refined

and adapted. Variations are being developed to monitor the freshness of poultry, meats, carbohydrates, and powdered baby formula.

All the new technologies in the world won't make a difference, says Ferenc, if other tried-and-true measures aren't routinely practiced. In short, regardless of technology, consumers need to choose food products carefully and handle and serve those products with care at home.

The Facts About Food Product Dating

Food product dating tells people certain information about specific foods, but there is no uniform or universally accepted dating system in the United States. Except for infant formula and some baby foods, product dating is not required by federal regulations. The following definitions should help you understand the dates that are voluntarily printed on various food products:

- "sell by": Tells the store how long to display the product for sale. Consumers should not buy the product after this date.
- "best if used by" (or "before"): Tells consumers how long the product will retain its best flavor or quality. (This is not a purchase or safety date!)
- "use by": Tells consumers the last date that is recommended for using the product while at peak quality. The manufacturer determines this date.
- "closed or coded": Represents packing numbers for use by the manufacturer to track inventory, rotate stock, or locate the product under suspicion of a problem. These dates do not indicate freshness or quality of the product.

Source: Food Safety and Inspection Service United States Department of Agriculture